

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human and Animal Subjects in Navy Research

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Comment

DON HRPP: The Pace Never Slows

This issue reports on the surge of DON HRPP actions and decisions in recent weeks and others anticipated through the summer. At press time, staff members started drafting the Department of the Navy Human Research Protection Program Handbook. The Handbook will provide the operating procedures and processes for every aspect of running a human research protection program.

Dr. Tim Singer, acting director of the Office of Naval Research's new Research Protections Division and a former Naval aviator, says that the Handbook will replicate the scope and tone of a Naval Air Training and Operating Procedures Standardization (NATOPS) manual that is used for training for flight procedures. The intent, he says, is to lay out in clear and concise language the fundamentals of running a human research protection program for all levels, ranging from the research staff to command leadership.

Meanwhile, the team is pushing ahead on renewals of Assurances for Navy commands that conduct human subject research. Many Assurances came due this spring; we've highlighted (RPU March and April) the revised procedures and requirements for requesting renew-

als of current Assurances and applying for new ones.

The Assurance application, directions, and self-assessment checklist are available on the Navy Medicine Online website (see page 3) and on a site just launched by the Research Protections Division of the Office of Naval Research. Both sites provide not only the requisite documentation, forms, and direction for the program, but also the historical and philosophical foundation for an enduring commitment to the protection of human subjects who participate in research—whether carried out under Navy sponsorship or in civilian settings.

The HRPP team also is working on a schedule of visits to research sites—a critical element in assessing a command's human research protection program. Late last year the team visited the Navy Experimental Diving Unit (RPU March), a Naval Sea Systems Command unit that falls under ONR's purview for HRPP oversight, and in March traveled to the National Naval Medical Center in Bethesda, Md., known as the Flagship of Navy Medicine. The site visits enable the team to conduct an examination of records, evaluate command awareness, and meet with Institutional

Review Board members and staffs. The visits aren't intended as bureaucratic surveillance—they're meant to support commanders and their HRPP staffs in meeting their responsibilities.

Navy HRPP professionals should check the websites and communicate any and all questions to the team.

The Navy leadership has endorsed human research protections as a top-level command mission. The HRPP leadership has mapped out an aggressive and proactive program for meeting the USN/USMC research protection mandate.

Also in this Issue:

National Research Winners

HRPP Websites Launched

National Naval Medical Center

DON Veterinary Affairs Office

Command Assurance Renewals

Navy Research Competitions

Cash, Jansen Win Navywide Research Competition

Cdr. Brooks Cash of the National Naval Medical Center Bethesda, and Lt. Tammy Jansen of NMC San Diego won the annual Navywide Academic Research Competition, held at the National Naval Medical Center in Bethesda, on May 12.

The competition, held for the 21st consecutive year, featured the winners of the regional competitions held in April at the NNMC and at the Portsmouth and San Diego Medical Centers in staff and resident categories (RPU May). Cash won the staff award; Jansen won in the resident category. The winners received engraved plaques.

Capt. Mark Olesen, acting NNMC Commander, and Cdr. John Gilstad of NNMC's Responsible Conduct of Research Department welcomed the presenters and guests.

Capt. Eileen Villasante, director of the Navy's Human Research Protection Program, offered a brief update on the DON HRPP program.

"We are responsible for overseeing all human subject research supported by the Navy and Marine Corps—not only the research being done at the major treatment facilities, but also that being conducted by the R&D labs and Systems Commands," Villasante said.

"One of our goals is to promote an understanding and awareness of human research throughout the Navy and Marine Corps. Ultimately, the information and technologies generated through human subject research are essential to protect the health of sailors, Marines, and their families, and to optimize the performance of

warfighters."

Rear Adm. Richard Shaffer DC (Ret.), Dr. Louise Jenkins, Associate Professor of Nursing at the University of Maryland, Dr. Steven Singh, Chief of Cardiology at the Veteran Affairs Medical Center in Washington, D.C., and Dr. David Tribble, an NMRC research scientist and chairman of NMRC Institutional Review Board, served as judges.

Cash spoke on "Risk Factors for Advanced Colorectal Neoplasia in Women: Comparison of the CON-CeRN and VA 380 Populations."

Jansen's topic was entitled "Will the Addition of a Sciatic Nerve Block to a Femoral Nerve Block Provide Better Pain Control Following Anterior Cruciate Ligament Repair Surgery?"

Lt. Sean Convoy of Portsmouth and Lt. Cdr. Matthew Provencher of San Diego also competed in the staff category. The other resident competitors were Lt. Chad Mao of NNMC and Lt. Daniel Weis of Portsmouth.

As at past competitions, investigators delivered a concise presentation of their research findings and answered questions from the judges and the audience. Topics ranged from new approaches to care of combatant casualties, to women's health and treatments of bone and nervous-system injuries.

Navy medical researchers are encouraged to submit abstracts for next year's competitions at the three medical centers, which usually are held in the spring. There will be a call for abstracts this fall.



First row: Cash, Jansen; second row: Gilstad, Olesen; third row: judges Tribble, Jenkins, Shaffer. U.S. Navy photo

Human Research Protection on the Web

DON HRPP and ONR Research Protections Online

The Navy's Human Research Protection Program (DON HRPP) and the Research Protections Division of the Office of Naval Research have gone online with information-packed websites that program officials say will expand dramatically the visibility of the Navy program.

The DON HRPP site on Navy Medicine Online, <http://navymedicine.med.navy.mil/humanresearch/>, launched in mid-May, provides concise sections on the program's background, mission and functions, links to issues of the **RPU** and applicable policy documents, including federal, DoD, and Navy documents, forms, and key contact information.

The site provides a description of the DON HRPP program that cites the signing of the Under Secretary of the Navy Executive Decision Memorandum as the effective start of the program. It describes the Surgeon General's role as the single point of accountability for assurances and program oversight.

The site offers all the relevant federal, DoD, and Navy policy instructions and other guidance that represent a comprehensive history of the program; it also

provides back issues of **RPU** and "News Blasts" that report on HRPP developments.

The ONR Research Protections Division site, http://www.onr.navy.mil/sci_tech/34/343/, which went live in late April, is hosted on the ONR public site within the command's Warfighter Protection Department (ONR 34).

The ONR site defines the Division's mission: to "ensure that the Navy and the Marine Corps conduct non-medical DON-supported human subject research in compliance with federal regulations, DoD directives, and Navy instructions" for the SYSCOMs, fleet and training commands, and extramural institutions that conduct Navy-sponsored research.

Like the DON HRPP site, the RPU site provides web links to policy guidance and information resources. It also describes the critical importance of human research to the mission of developing systems required by Navy and Marine Corps warfighters—that is, the mission that underpins the unique role ONR will take in ensuring the safe treatment of human subjects.



Naval Health Research Center, San Diego, is developing an internet-based tool for alcohol risk assessment and other health promotion topics. US Navy photo

Flagship of Navy Medicine

NNMC Mission: Fleet Support, Clinical Care, Research

In late March, the DON HRPP visited the National Naval Medical Center (NNMC) to evaluate the command's program.



NNMC Tower

The NNMC, long called the “Flagship of Navy Medicine,” provides Navy force health protection and operational readiness and graduate medical and dental education, and conducts a wide range of innovative medical and dental research. In 1938, Congress appropriated funds for a new Naval medical center. President Franklin Roosevelt laid the cornerstone on the new NNMC tower in November 1940.

The Center, when it opened in 1940, consisted of a 1,200-bed Navy hospital, medical and dental schools, and the Naval Medical Research Institute. By the end of World War II, the hospital had been enlarged to accommodate more than 2,400 sailors and Marines.

In 1973 the NNMC mission was expanded to encompass health-care services throughout the Naval District of Washington, giving the NNMC commander responsibility for all regional Navy health-care facilities.

Additional facilities were built in the late 1970s. The original NNMC tower has been designated a historical landmark on the Department of the Interior's National Register of Historic Places.

In August 2005, the Base Realignment and Closures Commission recommended that the Walter Reed Army Medical Center, in Washington D.C., be closed and its operations integrated with those of NNMC. The consolidation of WRAMC and NNMC, scheduled for completion in 2011, will expand NNMC facilities and services dramatically. In recent years, NNMC has led the nation's response to care for casualties of Operations Enduring Freedom and Iraqi Freedom. NNMC has treated hundreds of personnel wounded in combat. In November 2003, Secretary of the Navy Gordon England awarded the hospital a Meritorious Unit Commendation, citing the staff for their outstanding medical care to wounded sailors and Marines.

NNMC personnel have been recognized internationally in the areas of breast cancer, obstetrics, neonatal intensive care, mother and infant care, cardiac care, surgery, and neonatal and perinatal medicine. The facility also provides world-class capabilities in spinal surgery, head and neck oncology, and total joint replacement.

NNMC's medical research programs are coordinated by the Graduate Education and Research (GEAR) center within the Graduate Medical Education directorate.

The center executes NNMC's responsible conduct of research mission, providing oversight for the center's clinical investigation activities and research with human subjects and animals, as well as support to individual researchers and members of the NNMC Institutional Review Board.

REMEMBER THE DATE!

November 14, 2006

***Human Research
Protection Programs:
DoD Unique Perspectives***

Washington, DC



DON Animal Research Protection Program

Introducing the DON Veterinary Affairs Office

By COL Mark Gold

CAPT Villasante recently invited me to start an animal column in this newsletter. As with anything, knowing where to start is always the chore. Looking through some old newsletter articles published by the Naval Medical Research and Development Command in the mid-1990s, I found articles from some of my predecessors which gave me a feel for what they had to say.

When I came across the first column from LTC Jack Bley (now retired), I saw that he started with an explanation of why his office did second-level review, his expectations for submissions, and an expression of his confidence in the local IACUC system. Ten years later it seems that the topics are as fresh today as they were for him.

Animal research still is under intense public scrutiny. The military services and DoD agencies are required to meet higher self-imposed standards than are our civilian counterparts.

Clearly, the reasons for doing things have not changed, and in a certain sense, the mechanisms have not changed much either. We still have a second-level review process, follow a standard protocol template, and even do an annual data call.

“Our office will continue to do second-level review as it has always done, in as minimally intrusive a manner as possible, while still meeting the intent and letter of the Instruction.”

What has changed is that our instructions have evolved to provide clearer guidance for our actions, brought about by a Government Accounting Office (GAO) investigation, numerous Freedom of Information Act (FOIA) requests, Congressional inquiries, updates in the Guide for the Care and Use of Laboratory Animal Medicine, and the great input of a whole new generation of Army veterinarians, Institutional Animal Care and Use Committee (IACUC) members and chairs, and scientists.

Today one simply need follow SECNAVINST 3900.38C (AR 40-33) line by line, and success is guaranteed. The protocol template synthesizes federal law, the “Guide for the Care and Use of Laboratory Ani-

mals,” USDA policy, and other requirements to ensure that we do not inadvertently overlook important issues.

Our office will continue to do second-level review as it has always done, in as minimally intrusive a manner as possible, while still meeting the intent and letter of the Instruction. To do this, we expect to get all dog, cat, nonhuman primate, and marine mammal protocols (including all amendments); reports of protocol suspensions and significant deficiencies; copies of annual USDA animal use reports; updates of AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) International accreditation status; and anything else listed in the SECNAVINST, as a minimum.

Jack Bley said that our role, “... does not remove the responsibilities from the IACUCs, nor does it imply that the IACUCs are not trusted.” I not only agree with Jack, I feel that the strong local IACUCs are the backbone of our whole Navy and DoD programs, providing close, responsive, and understanding oversight of our animal care and use where it is needed most, in the labs.

We have no intention of directing any IACUC—our role is strictly administrative. We review protocols and do site visits to ensure compliance with SECNAVINST 3900.38C, but more than that, I also see our role as the “server of a network,” getting in information from all the users, passing along to them the best information, and making sure that the local users are not out there alone. This “server and network” concept adds tremendously to the whole program, but only works if the users are linked into our office, and willing to share information.

While the SECNAVINST checklists make the semi-annual facility inspection/program review (FIPR) a breeze, and the narrative clearly defines individual responsibilities, we are always available to provide a “read” of any issues, or assist in getting answers to the

(Continued on page 6)

Col. Mark Gold, USA is director of the Office of Veterinary Affairs of the DON HRPP. He'll be writing a regular column on animal care policy issues for Research Protections Update.

Command Assurances Approved

The Navy Surgeon General approved Assurances for the following commands for a period of three years:

The **Naval Medical Research Center** (NMRC), in Silver Spring, Md. oversees a wide range of Navy medical research efforts, with directorates managing programs in infectious diseases, biological defense, and combat-casualty care. It also supports research services departments in Pathology, Laboratory Animal Medicine and Science, and Clinical Diagnostics.

The **Naval Medical Research Center Detachment** (NMRC Detachment) in Lima, Peru has been hosted in Lima by the Peruvian Navy since its establishment in 1983. The laboratory conducts research in virology, entomology, bacteriology, and parasitology. It collaborates on

many research projects with local health organizations, including the Peruvian armed forces and Ministry of Health, as well as with the U.S. NIH, U.S. AID, and Centers for Disease Control, among others.

The **U.S. Naval Medical Research Unit No. 3** (NAMRU-3), established in 1946 in Cairo, Egypt, conducts medical research in support of U.S. forces deployed in and around the Middle East, Africa, and Southwest Asia. NAMRU-3 personnel have done extensive work on enteric diseases, virology, vector biology, and parasitology. The lab works closely with the Egyptian Ministry of Health, the U.S. National Institutes of Health, and international health programs.



(Left) Medical student researcher testing serum samples collected from humans with febrile illnesses in NMRC Detachment's main laboratory in Lima. U.S. Navy photo (Right) NMRC Detachment's logo.

Introducing the DON Veterinary Affairs Office

(Continued from page 5)

hazy gray questions, or even help you redistribute animals, caging, or other equipment to create efficiencies across the Navy and DoD.

I recently drafted a new OPNAVINST which will serve as an SOP for the Navy. It implements SECNAVINST 3900.38C and provides points of contact, guidance, and expectations for all programs.

The staffing process is long and arduous so I can't tell you when it will hit the street. Until that time, I hope that you will continue to contact our office at

202-762-0253 or 202-762-0252.

We want to wish SFC Javier Ruiz fair winds and following seas as he departs the BUMED Office of Veterinary Affairs for duty as the Operations NCO at the Southern California District of VETCOM. His contributions will long be remembered. In his place, we welcome SSG Damien James aboard as our new NCOIC. SSG James joins us from the Allegheny District of VETCOM, where he served as the NCOIC of Veterinary Services, Selfridge Air National Guard Base.

HRPP Questions and Answers

Military as IRB Members and PIs, Conflicts of Interest

The proposed SECNAVINST 3900.39D notes that Navy IRB members and PIs for DON-supported intramural research must be current federal employees. Is there an intent to prohibit military personnel from acting as either an IRB member or PI?

Military personnel are considered federal employees and therefore can serve as IRB members and PIs.

The proposed SECNAVINST 3900.39D paragraph on conflict of interest (see relevant text, below) appears to prohibit Navy inventors from participating in any human subject research to test or apply their inventions because the testing may lead to financial returns. Is that the intent?

*Excerpt from SECNAVINST 3900.39D (Draft) 6b. **Conflict of Interest.** Conflict of interest can be defined as any situation in which financial or personal*

interests may compromise or present the appearance of compromising an individual's or group's judgment in conducting, reviewing, approving, managing, and supporting research. Investigators, key research personnel, IRB members, and other personnel must disclose all conflicts of interest, including any financial interests for themselves, spouses, and dependent children. No person shall be involved in any review or approval of a protocol when there may be an apparent, actual, or potential conflict of interest.

The intent of this paragraph is to broaden the applicability of conflicts of interest beyond financial returns to investigators. All individuals who conduct, review, approve, support, oversee, or manage human subject research must disclose and report conflicts of interest. Institutions and IRBs must ensure there are appropriate plans to manage conflicts that are disclosed upfront or identified during review of research protocols.

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Wednesday, 14 June 2006, 1100 – 1200

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